

REMARKS

Claims 1-4, 7, 9, 10, 12-14, 17, and 19 are currently pending in this application.

REJECTIONS UNDER § 102 AND § 103

Claims 1 and 10 were rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,746,716 (“Vigil ’716”) in view of U.S. Patent No. 6,009,877 (“Edwards”). Applicants respectfully request reconsideration of this rejection.

Independent claims 1 and 10 recite dispensers “consisting only of dispensers positioned in a single plane.” The Office Action concedes that Vigil ’716 does not disclose this feature. However, the Office Action turns to Edwards for its alleged teaching of “dispensers 90 [that] are located in a single plane (see Fig. 14) to allow for treatment of a limited and precise area of the lumen while minimizing trauma to the lumen and the surrounding area.” As such, the Office Action suggests that it would have been obvious to modify Vigil ’716 to include dispensers in a single plane as allegedly taught by Edwards. Applicants respectfully disagree and request reconsideration, for the reasons given below.

[A]. The Combination of Vigil ’716 with Edwards is Improper.

Vigil ’716, which has two common inventors as well as common ownership with this application, is directed to the delivery of medication into the walls of blood vessels. (Vigil ’716, col. 1, line 9). The present invention arose out of the inventor’s recognition that devices such as in Vigil ’716 can lead to a blood vessel condition known as “restenosis,” increased permeability and increased blood flow. (Specification, paragraph 8). The inventors came up with the idea that these blood vessel issues could be alleviated with dispensers positioned in a single plane oriented substantially perpendicular to the axis of the catheter shaft. (Specification, paragraph 13).

The Applicants respectfully submit that the Edwards reference is unrelated both to the procedure of Vigil ’716 and to the problems sought to be addressed by the inventors. Whereas the device of Vigil ’719 is designed for delivering medicament to blood vessels, the device of Edwards is designed for addressing gastroesophageal reflux disease (GERD) in the esophagus. As background, Edwards explains that GERD is due to a dysfunction of the lower esophageal

sphincter (LES).¹ Edwards further discloses that one of the possible causes of GERD may be aberrant electrical signals in the LES.² As such, Edwards provides a device for treating a gastrointestinal sphincter, such as the lower esophageal sphincter. The device operates by delivering energy, such as RF energy, to the target site.³ For example, FIG. 14 of Edwards (as pointed out by the Office Action) shows a basket assembly having needle electrodes 90 for delivering RF energy to the target tissue.⁴

A person of ordinary skill in the art seeking to reduce tissue injury caused by medication injectors on a device for treating blood vessels as in Vigil '716 would not look to the teachings regarding an RF-delivery electrode on a device for treating the gastrointestinal sphincter as in Edwards. The device of Edwards is for treating a different part of the body for a different disease condition. Blood vessels differ from the esophagus in their structure, function, tissue composition, and dimensions. The cardiovascular disease addressed in Vigil '716 is completely different in its causes, symptoms and treatments from GERD and aberrant electrical signals in the LES, as addressed by Edwards.

As just one example, the average diameter of a coronary artery in an adult is reported to be between 2.7 – 4.9 millimeters (see the Abstract in attached Exhibit A, entitled “Echocardiographic Visualization of Coronary Artery Anatomy in the Adult”). In contrast, the average diameter of the esophagus, at the point of the lower sphincter, is reported to be 1.6 – 1.9 centimeters (see pg. 1359, col. 2 in the attached Exhibit B, entitled “Anatomy of the Esophagus”). Being on a much smaller dimensional scale, blood vessels require more precisely directed treatment than the esophagus. For example, Edwards suggests that the needle electrodes 90 in the device of FIG. 14 should penetrate to a depth of 0.5 – 5 mm for treating the esophagus.⁵ For a coronary artery, however, tissue penetration to this depth could cause a catastrophic perforating injury.

Furthermore, whereas the device of Vigil '716 has injectors for injecting medications, the device of Edwards uses electrodes for delivering energy, such as RF energy. Again, a person of ordinary skill in the art working with the medication injectors on the blood vessel treatment device of Vigil '716 would not look to Edwards for its teachings of RF-delivery electrodes.

¹ See, e.g., col. 1, lns. 29-32.

² See, e.g., col. 1, lns. 53-55.

³ See, e.g., col. 8, lns. 22-46.

⁴ See col. 9, lns. 48-60.

In summary, a person of ordinary skill in the art working with the medication injectors on the blood vessel treatment device of Vigil '716 would not look to Edwards, which teaches a device for treating a different part of the body (esophagus, instead of blood vessels) having a different dimensional scale (centimeters width, instead of millimeters), and using a different treatment modality (electrodes for delivering RF energy, instead of injectors for injecting medications). Rather, such a skilled person seeking to improve the device of Vigil '716 would look elsewhere, such as among the many references within the field of devices for delivering medication for treating cardiovascular conditions within blood vessels.

[B]. Edwards Provides No Reason for Adding a Single Plane Arrangement to Vigil.

The Office Action suggests that a person of ordinary skill in the art working with the Vigil '716 device would find improvement from the device of Edwards. According to the Office Action:

Edwards teaches that the dispensers 90 are located in a single plane (see Fig. 14) to allow for treatment of a limited and precise area of the lumen while minimizing trauma to the lumen and the surrounding area (Col. 3, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Vigil to include dispensers in a single plane only as taught by Edwards to minimize injury to the body lumen.

(Office Action, para. 3).

In addition to the fact that Edwards does not disclose “dispensers” but rather RF electrodes (as discussed above), Applicants respectfully submit that the teachings from Edwards referred to in the Office Action have absolutely no applicability to the Vigil '716 procedure. The Office Action cites column 3, lines 36-39 of Edwards, which states:

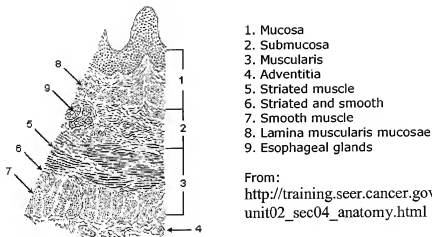
Yet another object of the invention is to provide a method to create cell necrosis in a sphincter and minimize injury to a mucosal layer of the sphincter.

(Edwards, col. 3, lines 36-39 (emphasis added)).

Cell “necrosis” refers to cell death which can be caused by heating through application of RF energy. (Edwards, col. 10, lines 32-37). In the passage above from col. 3, lines 36-39 of Edwards, which was cited by the Examiner, Edwards describes the object of creating cell

⁵ See col. 9, lns. 54-57.

necrosis in a sphincter and minimizing injury “to a mucosal layer” of the sphincter. The “mucosal layer” refers to a layer of the esophageal wall that is closer to the inside of the esophagus than the muscularis layer, which is made up of striated and smooth muscle. A diagram of the esophageal wall is shown below (the layers at the top of the diagram are closer to the inside of the esophagus):



From:
http://training.seer.cancer.gov/ss_module07_ugi/unit02_sec04_anatomy.html

The Edwards device minimizes injury “to a mucosal layer” by, for example, penetrating the RF electrode all the way into smooth muscle and insulating the electrode so as to minimize RF energy applied to the mucosal layer. This is shown in Fig. 13 of Edwards, reproduced below:

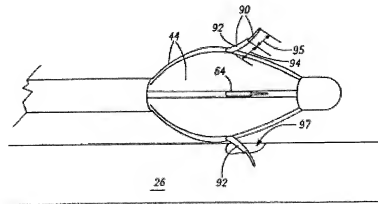


FIG. - 13

Edwards states:

Insulated segment 94 is of sufficient length to extend into sphincter wall 26 and minimize the transmission of RF energy to a protected site 97 near or adjacent to insulated segment 94 (see FIG. 13).

(Edwards, col. 3, lines 36-39 (emphasis added)).

In Fig. 13 above, the arrow for the “protected site 97” points to the mucosal layer. This is further shown in Fig. 23 of Edwards, reproduced below:

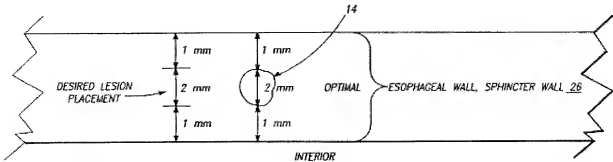


FIG. - 23

With reference to Fig. 23, Edwards states:

In one embodiment, a 2 mm diameter lesion 14 centered in the wall of the smooth muscle provides a 1 mm buffer zone to prevent damage to the mucosa, submucosa and adventitia, while still allowing for cell infiltration and subsequent sphincter tightening on approximately 50% of the thickness of the wall of the smooth muscle (refer to FIG. 23).

(Edwards, col. 12, lines 6-12).

Thus, as is clear from the above Figures and excerpts from Edwards, the passage from Edwards on which the Office Action relies, i.e., col. 3, lines 36-39 of Edwards, refers to the object of minimizing injury “to a mucosal layer” of the sphincter, and Edwards accomplishes this object by, for example, having deep RF electrode penetration coupled with insulation techniques. Therefore, if one were to follow the logic of the Office Action that a person of ordinary skill in the art would look to Edwards for its teachings regarding minimizing injury, the only legitimate logical next step is that such a person would take from Edwards its solutions for that are described for minimizing injury, e.g., having deep RF electrode penetration coupled with insulation techniques. These solutions, however, are applicable to the RF procedure of Edwards but not to the medication dispensing procedure of Vigil ’716. Applicants respectfully submit that neither the objective of Edwards (minimizing injury to a mucosal layer) nor these solutions

from Edwards (deep RF electrode penetration coupled with insulation techniques) have any relevance to the Vigil '716 procedure.⁶

For at least these reasons, Applicants respectfully submit that there is no reason in the Vigil '716 or Edwards references or elsewhere within the prior art to make the modification of Vigil '716 as proposed in the rejection. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 1, 14, 82 USPQ2d 1385 (2007). Accordingly, Applicants respectfully submit that the claims are non-obvious over Vigil '716 in view of Edwards, and withdrawal of the rejection is respectfully requested.

[C]. Other Obviousness Rejections

Various other dependent claims in this application were rejected under § 103(a) as being unpatentable over Vigil '716 in view of Edwards, and further in view of Rammler (WO 94/23787), or Goldberg et al. (U.S. Patent No. 5,480,975), or Casscells et al. (WO 92/11872), or Nabel et al. (U.S. Patent No. 5,328,470).

Without conceding that the Office Action's characterization of these secondary references is correct, Applicants respectfully submit that none of these secondary references disclose dispensers "consisting only of dispensers positioned in a single plane," as recited by claims 1 and 10. Therefore, these secondary references do not cure the above-mentioned deficiencies of Vigil '716 and Edwards. Further, there is nothing in any of these secondary references that would prompt a person of ordinary skill in the art to arrange the dispensers in the manner recited by claims 1 and 10.

For at least these reasons, Applicants respectfully submit that claims 1 and 10, and the claims that depend therefrom, are non-obvious over the references cited in the rejection. Accordingly, withdrawal of the rejections is respectfully requested.

⁶ In addition, with reference to Figure 16, which is not cited by the Office Action, Edwards states that the emergence angle 96, the arc radius 98, the amount of clearance between the aperture inner diameter 102 and the needle electrode outside diameter 104, and the use of a lubricous coating on electrode delivery member 60 can be utilized, not once stating any relationship between a single plane arrangement and avoiding tissue injury. See Edwards, col. 10, lns. 2-20.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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Date: 24 February 2009

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